**Planning and Navigation Assistance using Two-dimensionally
Adapted Generic and Detected Patient Data**

RELATED APPLICATION DATA

5   This application claims priority of U.S. Provisional Application No.
60/494,935 filed on August 13, 2003, which is incorporated herein by reference in
its entirety.

FIELD OF THE INVENTION

10   The present invention relates to a method and device for
computer-assisted medical navigation and/or pre-operative treatment planning. In
particular, it relates to a method and device for planning and navigation
assistance using two-dimensionally adapted and detected patient data.

15   **BACKGROUND OF THE INVENTION**

        Computer-assisted, stereotactic systems, which work with the aid of body
structure data obtained from tomographic detection systems and with the
assistance of x-ray images produced in situ are known, for example, from U.S.
Patent Nos. 4,791,934 and 5,799,055. X-ray imaging used to assist in operations
20   is discussed in U.S. Patent Nos. 5,967,982, 5,772,594 and 5,784,431.

        Referencing the current position of the structures to be operated on by
means of pre-operatively produced three-dimensional patient data and x-ray
images produced in situ (fluoro-CT matching) is introduced here as a non-contact
method, which is therefore suitable for minimally invasive surgery.

25   Where accurate medical navigation is to be provided, the prior art still
works with the aid of body structure data originating from tomographic detection
systems, such as, for example, computer tomography devices or nuclear spin
tomography devices. The patient to be treated is thus positionally registered in
situ with respect to the image data determined beforehand. Operating
30   instruments are then virtually displayed in the same relation to the image data as
to the actual patient, to make the body structure data or, if possible, also x-ray
image data useful to the surgeon in the operating room.

Disadvantages of such methods, in which tomographs (CT, MR) or x-ray images are produced, especially for navigating within the framework of treatment, include the radiation load on the patient and the high costs, since such devices are very expensive both to purchase and to maintain and operate.

5   Attempts have been made to develop systems that may be employed without body structure data separately detected beforehand, for example, based on statistical models of image data sets for body structures. However, such systems lack the required accuracy for the respective patient to be treated.

DE 100 37 491 A1 and WO 99/59106 describe methods for providing 3D

10   information with the aid of fluoro-images. The starting point in all methods is recording transillumination images of the patient or of the desired structure. A localization system is used to obtain spatial information using the images. DE 100 37 491 A1 initially uses two fluoro-images, from which to reconstruct a rough 3D model. Other images from different angles are used to specify the model

15   more precisely. In accordance with WO 99/59106, at least three fluoro-images of the patient are generally made. These are anterior-posterior, lateral and anterior-posterior with the head inclined backwards. In addition to the transillumination images, photographs of the patient are also used. In this prior art, the model is painstakingly adapted in three-dimensional space.

20

SUMMARY OF THE INVENTION

In accordance with one aspect of the invention, a method for computer-assisted medical navigation or pre-operative treatment planning can include detecting a position of a patient or a part of a patient's body and detecting

25   positions of medical treatment devices or treatment-assisting devices. The method can further include assigning the detected positions to body structure data, the body structure data being obtained from a three-dimensional generic model.

30   **BRIEF DESCRIPTION OF THE DRAWINGS**

These and further features of the present invention will be apparent with reference to the following description and drawings, wherein:

-2-

Fig. 1 is a flow diagram illustrating a method for registering and adapting a generic model in accordance with the invention; and

Figs. 2 to 6 are exemplary screen shots of a computer application which assists the method in accordance with the invention.

DETAILED DESCRIPTION OF THE INVENTION

In accordance with one aspect of the invention, the current position of a patient or a part of a patient's body and the positions of medical treatment devices or treatment-assisting devices can be detected in such navigation methods by means of a position detection unit, and the detected positional data can be assigned to body structure data, in order to jointly use the body structure data in assignment with the positional data, within the context of assisting the treatment. Such a navigation system is described for example in DE 196 39 615 C2 and corresponding U.S. Patent No. 6,351,659, which is incorporated herein by reference in its entirety.

In accordance with one aspect of the invention, the invention is directed to a method for computer-assisted medical navigation and/or pre-operative treatment planning. The method can avoid producing a separate image data set, which is cost-intensive and a burden to health, for navigation/treatment planning, while nonetheless providing sufficiently accurate navigation.

In accordance with one aspect of the invention, in a computer-assisted medical navigation method and/or treatment planning method, body structure data is used. The body structure data can be obtained based on a generic model, which has been adapted by linking it with patient-characteristic detection data, such as pre-operatively or intra-operatively obtained x-ray image data.

If the x-ray image data includes more than one image from different directions of projection, then these two-dimensional summation images can be in a known or calculable navigational relationship to each other.

On the basis of this known relationship, a three-dimensional generic model is superimposed onto the patient-specific x-ray images, and a projection of this model is adapted to the respective x-ray images. The model can be adapted in

two-dimensional space, unlike other described methods, which employ two-dimensional patient-specific data to create a three-dimensional model.

When adapting in this way, the projection of anatomic landmarks or geometries, such as the edges of bones or typical osseous borders and anatomical structures (for example, the processus transversus and spinosus of a vertebra, or the projected course of the pedical in a vertebra model), are automatically or manually identified. Projecting the stored model structures is then adapted to these two-dimensionally identified landmarks.

This adaptation requires a guideline for transforming the model onto the patient-specific data, which also enables the information stored in the model, for example, a CT or MR data set, to be appropriately modified, such that a "virtual" data set of the patient, including tomographic images, can be used for navigation.

By calculating the projection, this data set can be displayed as digital reconstructed radiography (DRR) and compared with the patient-specific data in order to automatically or manually verify the model.

In one embodiment, two transillumination images are sufficient. It is advisable to record these perpendicular to each other, such as, for example, in the case of anterior-posterior and lateral images, though other angles are not a problem. Other transillumination images can, however, also be incorporated in order to make the model more precise.

In one embodiment, the generic model is pre-defined. It can contain information on the deforming models used and their interrelationships, as well as landmarks or other points of interest, which can be used to deform the model. The model can include either a surface model or a tomographic data model or a combination of both. One advantage of the surface model is that it is simple and quick to deform, which makes it particularly suitable for real-time applications. Tomographic data models are required for specific visualization and provide extended information on the volume of a structure.

In order to use the three-dimensional model in conjunction with the transillumination images, it has to be adapted ("morphed") to the information of the images. In one embodiment, the landmarks and other points of interest, which are used for deforming, are projected onto the two-dimensional

-4-

transillumination images. The deformation of the model is defined by adjusting the predetermined landmarks to the contour of the desired structure.

The landmarks do not have to be identified in more than one transillumination image. The prerequisite that at least two images are required in order to establish the position of the landmarks, as is required in the prior art, does not apply to the method described herein. It is sufficient if the landmarks are placed in just one of the images. Contrary to the conventional method as set forth in DE 100 37 491 A1, a rough model is not produced from the projections, since the model in the method in accordance with the invention is predefined and, therefore, can be optimized for precise displaying. The number of landmarks to be identified is also substantially lower than in the method as set forth in WO 99/59106. For the example of the spine, at most, 20 landmarks are required.

The tomographic image data can be predefined together with the model, and further pre-operative tomographic imaging does not have to performed.

Since the model used represents a predefined reference of the structure to be visualized, it only has to be adapted to the transillumination images. One advantage for the surgeon is that he obtains a precise 3D representation of the desired structure, irrespective of the number of transillumination images and without having to fall back on elaborate and costly tomographic image data (MR).

In methods such as those described in the specifications of DE 100 37 491 A1 and WO 99/59106, the precision in registering the desired structure is dependent on placing the landmarks and/or identifying the contour in the transillumination image. In the method in accordance with one embodiment of the invention, this error can still be minimized. To this end, the transillumination data predefined with the generic model are used. The deforming guideline, generated from the information of the transillumination images, is then applied to the tomographic data. A tomographic image data set, adapted to the patient, can be obtained. Using a fluoro-to-CT matching algorithm, the deformed tomographic image data set can then additionally be registered. This minimizes inaccuracies that can arise from manually or automatically placing the landmarks. With the aid of this step, the precision of the method can be substantially increased and reliability can also be improved. The precision of the fluoro-to-CT matching

method has been demonstrated in a number of studies, and the results of this algorithm are easily verified.

When "navigation" is mentioned in the following, this term is intended in principle to also include pre-operative treatment planning in the context of which a surgeon determines an ideal approach for a treatment beforehand, for example, manually determines and fixes the ideal position of an implant.

The advantages of the present invention are based, among other things, on the fact that by using a generic model adapted to the patient, it is no longer necessary to produce a separate data set for the body structure, for the treatment for which medical navigation is to be provided. This spares the patient the radiation load as well as saves the costs of producing the data set (for example, by tomography). In addition, linking the generic body structure data with patient-characteristic detection data provides a data set which enables highly accurate medical navigation. The generic model, which can be a kind of universal model for the body structure in question, for which all the relevant data is available, does not include data tailored specifically to the patient in question, but does include sufficient anatomical and/or body structure data to be able to provide a sufficiently accurate basis for medical navigation, once it has been adapted with the aid of patient-characteristic detection data.

It is possible within the framework of the present invention to provide the body structure data in the form of an image data set, such as a tomographic imaging data set.

In this way, separate image detection data sets are not generated, as in methods in accordance with the prior art. Rather, the generic model itself is already provided in the form of an image data set, which can then be adapted to the respective patient, to obtain an image data set that is valid for the patient. The image data set is adapted by way of superimposing, for example, patient-specific x-ray images, which represent a two-dimensional summation image from a defined direction of projection, and projecting the three-dimensional generic model onto said summation image.

The projection of the model onto the patient-specific data is adapted using knowledge of the three-dimensional, model-specific interdependence between

anatomical landmarks and structures. Thus, manual or automatic shaping between the model and the patient data can, depending on the structure, correspond to shifting, deforming or rotating the model, or to a combination of these.

5 　　　　The deforming, shifting or rotating guideline thus obtained for the model can then be applied to the information stored in the model, to generate a three-dimensional image data set or to deform an already existing image data set with the aid of the guideline.

　　　　This image data set can then be employed just like one produced
10 cost-intensively and with pre-operative radiation load for the patient. It is conceivable, for example, to use a generic model comprising a typical or average body structure, for example, a simple model representation of a vertebra, humerus, radius or ulna, femur, tibia or pelvic bone, or another osseous body structure.

15 　　　　The generic model can also include a statistical model of the body structure, such as one based on statistical evaluations of an indefinite number of image data sets, for example, of actual vertebra image data sets.

　　　　Furthermore, the possibility exists of providing the generic model directly as a kind of model package for a multitude of body structures of the same type.
20 In this case, it is possible when adapting the model to isolate from the multitude of models in the package the one that best matches the patient-characteristic detection data, such that the model only has to be slightly adapted with computer assistance.

　　　　Within the framework of the present invention, the generic model can
25 include a two- or three-dimensional data set of a body structure, also a geometric model. In other words, the generic model can include both three-dimensional data (for example, a vertebra model) and two-dimensional data (for example, virtual x-ray images) or also a model in the form of geometric data. This data can, for example, be angles and/or trajectory information, which can be displayed for
30 the physician and indicate to him the ideal position of an implant.

　　　　Various types of patient-characteristic data are outlined in the following, such as can be used for adapting the generic model. It is also always possible to

employ combinations of such data, referred to as diagnostic data in the following, to this end.

The patient-characteristic data can be x-ray data, from x-ray images produced before or during treatment, such as bi-planar or multi-planar x-ray images. An example of this is when x-ray images of the patient are already available, which were produced within the context of previous examinations. Data about body structures from these "old" x-ray images is particularly suitable if deviations of form with respect to the generic model are to be calculated in.

It is, however, also possible, even during treatment, to produce individual x-ray images of the patient and to include this information in adapting the generic model. The advantage as compared to conventional "x-ray navigation" is then that it is not necessary to produce a large multitude of x-ray images, such as are used in navigation based on x-ray images. It is sufficient for adapting the generic model to produce just one or very few x-ray images, which, moreover, can be restricted to a very small section of the body. This significantly reduces the radiation load as compared to conventional x-ray navigation.

The above applies in the same way to computer tomography or nuclear spin tomography image data. Data may be used, which is derived from tomographic images produced much earlier, but whose information is sufficient for suitably adapting the generic model.

Moreover, the diagnostic image data can also be digitally reconstructed x-ray image data (DRRs = digitally reconstructed radiographs), which can, for example, be produced from tomographic image data sets already available, without the patient again having to be subjected to x-ray imaging.

It is, however, not absolutely necessary to use complicated, patient-characteristic detection data and/or diagnostic data in this way, to be able to adapt the generic model sufficiently. It can be sufficient to use acquired point-positional information of the patient's body structure, such as natural or artificial landmarks. The patient-characteristic diagnostic data can then, for example, be the distance between two landmarks (for example, apophyses), which alone can give sufficient information about how the generic model should

be restructured. Similarly, data on size, weight or lengths of the body section or of one or more limbs of the patient can be used as a basis for this.

The generic model can be adapted within the context of the invention using one or more of the following methods: manually adapting with the assistance of image representation, such as by offsetting points and landmarks or by shifting, rotating, stretching or compressing the generic model on a screen output by means of user-interface means; automatic image fusion methods, for example, based on automatically identifying particular anatomical features; and registering and/or fusing image data of the generic model, such as digitally reconstructed x-ray images, and the same from computer tomography or nuclear spin tomography image data sets.

The generic model can thus be fused using diagnostic methods either automatically, for example, by automatically identifying particular anatomical features critical for fusion, or manually, for example, by shifting, rotating and/or stretching. When the generic model is fused with actual patient information by acquiring an indefinite quantity of point information on the patient (landmarks), it is possible to use a so-called surface-matching method, i.e., a computer-assisted image adapting method, to fuse the image data. From the various methods described above, capturing the diagnostic data and adapting the generic model are combined in accordance with one embodiment of the invention, such that alongside the diagnostic data (for example, x-ray images acquired intra-operatively), additional points on the patient are also recorded, in the form of landmarks or randomly acquired points, and used to detect and adjust the position of the model or its form even more accurately, so as to enable more accurate navigation.

A hip-thigh arrangement (pelvis/femur) can also be registered by means of registered x-ray images and a generic model. The hip could then be registered, for example, by assigning landmarks between the generic model and one or more x-ray images (fluoroscopy, for example at an angle of 30°) by mathematical coupling.

Generally speaking, the positional data obtained while determining the patient-characteristic detection data, such as by acquiring landmark positions or

by x-ray imaging registered in the navigation system, can be used to register the adapted body structure data in the navigation system and to visually display or introduce treatment devices and/or treatment-assisting devices in their registration to the adapted body structure. In other words, the step of capturing the diagnostic data is also simultaneously used in this way to register the patient and the adapted generic model for navigation. As long as the data of the model is fused with registered data, i.e., data which is clearly determined in the spatial position, such as registered fluoroscopy images of an x-ray navigation software, or the data of the model are registered with landmarks, or a combination of the two methods, these can be used for computer-assisted surgery and, for example, for minimally invasive operations in which instruments or implants are displayed in relation to a fused model.

The method described herein can be used both to assist in surgery in which the surgeon is provided with navigating aids on screens, and within the context of radiotherapy and/or radiosurgery. Navigation can be based on optical tracking or on magnetic tracking.

The present invention can include a program which, when running on a computer or loaded on a computer, causes the computer to perform one or more of the methods described above, and a computer program storage medium comprising such a program.

In summary, it may further be stated with respect to the above invention that it reduces the radiation load and eliminates or at least minimizes the costs of tomographic imaging methods, and that it also has the advantage as compared to pure x-ray navigation that it enables the surgeon three-dimensional navigation and orientation. Further advantages lie in the fact that the steps resulting in the patient being registered are substantially less complicated and the patient can be registered using few manual steps. Costly diagnostic examinations are simplified, and acquiring points/landmarks on the patient for registering can also be made superfluous, if already calibrated data (for example, registered x-ray data) are used and additional useful information is obtained through fusion with the generic model (for example, converting a quantity of two-dimensional information into actual three-dimensional information).

It is thus possible in accordance with the invention to automatically display the ideal position of implants or instruments at little cost, such that surgery can be performed more quickly, more securely, and less invasively.

With reference now to Fig. 1, a flow chart illustrating a method for registering and adapting a generic model is provided. It is to be appreciated that the method illustrated in Fig. 1 is described in greater detail above. The method can include recording one or more two-dimensional fluoro-images at step 10 and selecting a predefined, available generic model at step 12. Step 16 can include projecting the generic model on the two-dimensional images, adapting landmarks in the two-dimensional images, and applying the appropriate deformation to the generic model. Step 20 can include applying deformation to the tomographic data belonging to the generic mode. Step 24 can include converting tomographic data into DRRs and performing fluoro-to-CT matching. At step 28, a model and tomographic data, which are more exactly and/or precisely registered, results. This makes surgical navigation possible using, for example, the tomographic data and a surface model.

Figs. 2-6 show screen shots of a computer application, which assists the method described herein, in accordance with one embodiment of the invention. Screen shots for two-dimensionally superimposing x-ray images and projections from generic models may be recognized, including highlighted landmarks of the model, which are placed on the corresponding points of the patient x-ray images by the operator, so as to ascertain a suitable transformation.

Fig. 2 shows two exemplary views of a hip model, while Figs. 3 and 4 show two exemplary views of a vertebra model, wherein only the landmarks are indicated. Fig. 5 shows exemplary views of a femur.

Once the transformation guideline is then ascertained and the generic model adapted, fluoro-navigation can be performed as shown in Fig. 6, on the x-ray images (top) and assisted by adapted generic 3D image representations (bottom).

Although the invention has been shown and described with respect to a certain preferred embodiment or embodiments, it is obvious that equivalent alterations and modifications will occur to others skilled in the art upon the reading

and understanding of this specification and the annexed drawings. In particular regard to the various functions performed by the above described elements (components, assemblies, devices, systems, compositions, etc.), the terms (including a reference to a "means") used to describe such elements are intended to correspond, unless otherwise indicated, to any element which performs the specified function of the described element (i.e., that is functionally equivalent), even though not structurally equivalent to the disclosed structure which performs the function in the herein illustrated exemplary embodiment or embodiments of the invention. In addition, while a particular feature of the invention may have been described above with respect to only one or more of several illustrated embodiments, such feature may be combined with one or more other features of the other embodiments, as may be desired and advantageous for any given or particular application.